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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,150	04/13/2004	Joseph M. Jilka	P04376US01	4559

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MCKEE, VOORHEES & SEASE, P.L.C.
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DES MOINES, IA 50309-2721

EXAMINER

SALIMI, ALI REZA

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,150

Applicant(s)

JILKA, JOSEPH M.

Examiner

A R. Salimi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2 and 4-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 29-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/13/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

8.02

DETAILED ACTION

DETAILED ACTION

Due to an apparent error on the part of the Office for not identifying the amended claims filed on 4/13/2004 and not recognizing that Applicant has opted to continue prosecution of the parent application in the current application, the previously mailed written restriction is now vacated. An action follows.

Response to Amendment

This is a response to the amendment filed 4/13/2004. Claims 1-34 are pending. Claims 1-2, 4-28 have been removed from consideration as they are directed to non-elected groups on the same grounds stated in the parent application 10/169,813. Claims 3, 29-34 are considered.

Applicant is reminded to cancel the claims to the non elected claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Please note any ground of rejection that has not been repeated is removed.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-

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part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please up-date the status of prior application(s).

Claim Rejections - 35 USC § 112

Claims 3, 29-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "less than the amount" and "reduced titer of virus infection" in claim 3 are relative terms which renders the claim indefinite. The said terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. This affects the dependent claims 29-34.

Claim Rejections - 35 USC § 112

Claims 3, 29-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protection of porcine against PRRSV by eliciting mucosal response when edible plant having TGEV antigens and within the limitations of main claim 3, does not reasonably provide enablement for a general method of vaccinating against all antigens of all virus types, i.e. HIV, EBOLA, Hepatitis, plague, typhoid, etc.... The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The scope of the claims are directed to vaccines, Applicants have general statements regarding the vaccine composition via edible plant where no serum antibody was observed and have taught

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challenge against PRRSV when antigen of TGEV was included in plant. However, the filed of vaccine development is highly unpredictable. To date no protective vaccine exists for HIV, and yet the scope of the claims read on the method of protecting the very virus. One of ordinary skill in the art would be forced to conduct large quantity of undue experimentations to enable the full scope of the claimed invention. Hence, with regard to an unpredictable field, this does not constitute an adequate disclosure. See *Fiers v. Revel* (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007). For example, the CAFC stated that “It is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of an invention in order to constitute enablement.” (See page 1005 of the decision). This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. Applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

Claims 3, 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al (WO 94/20135), for reasons of record advanced in the previous Office Actions mailed 10/7/03; 10/14/03 in the parent application 10/169,813. Applicant’s entire argument revolves around the

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fact that Lam et al on page 8, lines 22-30 has indicated that the immunogen prime the mucosal immune system and/or stimulate the humoral immune response, in a dose -dependent manner.

Applicant concludes that since Lam et al discloses an antibody response it does not anticipate the claimed invention. Applicant further asserts that, Applicant discloses on page 31 at line 1, that “according to the invention, however dosing is accomplished at much lower levels, only sufficient to generate protection, without an antibody response.” Applicant additionally directs the Office to Table 1, and Table 2 where the serum antibodies levels were identical to the control corn group. Applicant’s argument as part of amendment filed 4/13/2004 has been considered fully, but they are not persuasive. First, Lam et al on page 8 indicates that the mucosal immune response and/or humoral immune response. The operative phrases are “and/or”, in addition to, “dose dependent manner” (emphasis added). It means it can be mucosal or humoral depending on the dosage. This is exactly what Applicant has done and has directed the Office to look to the disclosure for recitations that have meaning in abstract only. For instance the limitations of claim 3 “less than an amount sufficient... by a reduced titer of virus infection...”, does not indicate anything that can be reasonably deciphered. What less than amount? What is sufficient to generate protection? The broad interpretation has been given to broad and indefinite limitations. Lam et al clearly taught as Applicant admits on the record oral vaccine introduced by consumption of a transgenic plant against a viral disease. The Lam et al anticipates the broad claimed invention. They taught the plant that is/are edible, have taught the antigen and they have induced protection via mucosal system, and depending on dose the system behaves accordingly. Applicant’s entire discovery is what has been disclosed in Table 1 and Table 2 only, however, if Applicant desires to claim a general method of protecting all animals against all viral pathogens

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then they have to overcome the above cited art. Applicant cannot have it both ways. Applicant cannot recite broad and indefinite claimed limitations and at the same time indicate that the limitations that are indefinite make the claimed invention novel. Lam et al is a pioneering invention, hence, they are entitled to a broad protection, they are teaching that if one wants mucosal response then one can achieve it by their method, and if one wants humoral response, then that can also be achieved, and all is needed is dosage calibration. This is exactly what applicant is asking the Office to consider, and this is exactly what applicant has done. Moreover, Applicant is directed to In re Cruciferous Sprout Litigation, 64 USPQ2d 1202 (CA FC 2002) wherein the Federal Circuit cited authority for the rule that, "a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." The rejection is respectfully maintained.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

6/23/2005


ALI R. SALIMI
PRIMARY EXAMINER